

Docket No. 10806-120

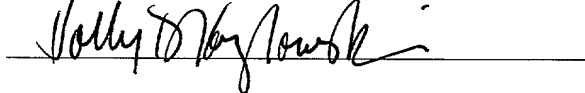
PATENT

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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant: Albert J. Pennings et al : Paper No.:
Serial No.: To be assigned : Group Art Unit:
Filing Date: April 10, 2001 : Examiner:
For: **Hydrogels and Methods for Their Production**

PRELIMINARY AMENDMENT

BOX Patent Application
Assistant Commissioner for Patents
Washington, DC 20231

Dear Sir:

Prior to calculation of the filing fee and first action by the Examiner, please amend the present application as follows:

In the Claims:

Please amend claims 1, 2, 7, 8, 12, 15, 16, 19-23, 26-30, 32, 33 and 35-42 to read as follows:

1. (Amended) A hydrogel comprising a network of hydrophilic polymers having hydrogel group-carrying carbon to carbon backbones and having a tensile strength of at least 1 MPa.

2. (Amended) A hydrogel according to claim 1 having an elasticity modulus less than about 10 kPa.

7. (Amended) A hydrogel according to claim 1, wherein the hydrophilic polymers have a molecular weight of at least 200,000.

8. (Amended) A hydrogel according to claim 1 having a polymer content of about 30 to 80% (wt).

12. (Amended) A hydrogel according to claim 1 wherein the hydrophilic polymer is at least one selected from the group consisting of $-(\text{CH}_2\text{-CHOH})_n$ - (polyvinyl alcohol); $-(\text{CH}_2\text{-CH}_2)_n(\text{CH}_2\text{-CHOH})_m$ - (copolymer of ethylene and vinyl alcohol); $-(\text{CH}_2\text{-CH}_2\text{-CHOH})_n$ - (poly(1-hydroxy-1,3-propanediyl)); and $-(\text{CH}_2\text{-CH}(\text{CH}_2\text{OH}))_n$ - (polyallyl alcohol).

15. (Amended) A hydrogel according to claim 14, wherein the crosslinking density is less than about 10%.

16. (Amended) A hydrogel according to claim 15 crosslinked by a diisocyanate.

19. (Amended) A hydrogel according to claim 19, wherein R is an optionally substituted lower alkyl group having one to ten carbon atoms.

20. (Amended) A hydrogel according to claim 19, wherein R is $-(\text{CH}_2)_4$ -.

21. (Amended) A hydrogel according to claim 14 crosslinked by an epoxy compound.

22. (Amended) A hydrogel according to claim 12, wherein the hydrophilic polymer is poly(1-hydroxy-1,3-propanediyl).

23. (Amended) A hydrogel according to claim 22 crosslinked with diisocyanate.

26. (Amended) A hydrogel according to claim 24, wherein the hydroxyl groups of poly(1-hydroxy-1,3-propanediyl) are modified with a monoisocyanate before being crosslinked with a lower alkyl diisocyanate.

27. (Amended) An implant made of a hydrogel according to claim 1.

28. (Amended) An ophthalmic lens made of a hydrogel according to claim 1.

29. (Amended) An ophthalmic lens according to claim 27 having

- (a) an elasticity modulus less than about 10kPa;
- (b) a tensile strength of at least about 1 MPa;
- (c) an elongation of at least 50% at equilibrium water content;
- (d) sufficient optical clarity so as to obtain an optical transmission of at least about 40%; and
- (e) a refractive index of at least about 1.40.

30. (Amended) A method of preparing a hydrogel having a low elasticity modulus from a hydrophilic polymer comprising the steps of:

- (a) selecting hydrophilic polymer of sufficiently high molecular weight;
- (b) dissolving said polymer in a solvent to a concentration not exceeding about 5% (wt);
- (c) adding a crosslinking agent;
- (d) mixing and reacting the polymer with the crosslinking agent; and
- (e) evaporating said solvent; and
- (f) optionally adding water.

32. (Amended) A method according to claim 30, wherein the hydrophilic polymer has a molecular weight of at least about 200,000.

33. (Amended) A method according to claim 30 further comprising degassing the solution of polymer in solvent.

35. (Amended) A method according to claim 30, wherein the hydrophilic polymer has hydroxyl group-carrying carbon-carbon backbone.

36. (Amended) A method according to claim 35, wherein the hydrophilic polymer is at least one polymer selected from the group consisting of $-(\text{CH}_2\text{-CHOH})_n$ - (polyvinyl alcohol); $-(\text{CH}_2\text{-CH}_2)_n(\text{CH}_2\text{-CHOH})_m$ - (copolymer of ethylene and vinyl alcohol); $-(\text{CH}_2\text{-CH}_2\text{-CHOH})_n$ - (poly(1-hydroxy-1,3-propanediyl)); and $-(\text{CH}_2\text{-CH}(\text{CH}_2\text{OH}))_n$ - (polyallyl alcohol).

37. (Amended) A method according to claim 35 further comprising modifying the hydrophilic polymer by reacting it with a mono-isocyanate.

38. (Amended) A method according to claim 37 comprising modifying less than 15% of the hydroxyl groups.

39. (Amended) A method according to claim 30 comprising performing the crosslinking at constant volume.

40. (Amended) A method according to claim 30 resulting in the formation of a hydrogel having an elasticity modulus less than about 10 kPa.

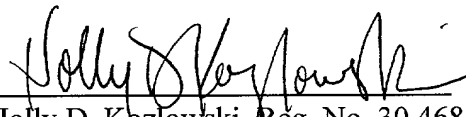
41. (Amended) A method according to claim 36 wherein the hydrophilic polymer is (poly(1-hydroxy-1,3-propanediyl)).

42. (Amended) A method according to claim 41 wherein the crosslinking agent is a diisocyanate.

REMARKS

By the present Amendment, the claims are amended to omit their multiple dependency and for various matters of form in accordance with customary U.S. patent practice. A "Version With Markings Showing Changes Made" is attached. It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

Respectfully submitted,



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VERSION WITH MARKINGS SHOWING CHANGES MADE

1. (Amended) A hydrogel comprising a network of hydrophilic polymers having hydrogel group carrying ~~carbon to carbon~~ backbones and having a tensile strength of at least 1 MPa.

2. (Amended) A hydrogel according to claim 1 having an elasticity modulus less than about 10 kPa[, preferably less than about 5 kPa].

7. (Amended) A hydrogel according to claim 1, wherein the hydrophilic polymers have a molecular weight of at least 200,000 [200 000, preferably at least 300 000].

8. (Amended) A hydrogel according to claim 1 having a polymer content [between] of about 30 to 80% (wt)[, preferably between about 40 to 70% (wt)].

12. (Amended) A hydrogel according to claim 1 wherein the hydrophilic polymer is [selected from] at least one [of the polymers] selected from the group consisting of $-(CH_2-CHOH)_n-$ (polyvinyl alcohol); $-(CH_2-CH_2)_n(CH_2-CHOH)_m-$ (copolymer of ethylene and vinyl alcohol); $-(CH_2-CH_2-CHOH)_n-$ (poly(1-hydroxy-1,3-propanediyl)); and $-(CH_2-CH(CH_2OH))_n-$ (polyallyl alcohol).

15. (Amended) A hydrogel according to claim 14, wherein the crosslinking density is less than about 10%[, preferably less than about 5%].

16. (Amended) A hydrogel according to claim 15 crosslinked by [means of] a diisocyanate.

19. (Amended) A hydrogel according to claim 19, wherein R is an optionally substituted lower alkyl group having [between] one [and] to ten carbon atoms.

20. (Amended) A hydrogel according to claim 19, wherein R is $-(CH_2)_4-$.

21. (Amended) A hydrogel according to claim 14 crosslinked by [means of] an epoxy compound.

22. (Amended) A hydrogel according to claim 12, wherein the hydrophilic polymer is poly(1-hydroxy-1,3-propanediyl).

23. (Amended) A hydrogel according to claim 22 crosslinked with [diisocyanates] diisocyanate.

26. (Amended) A hydrogel according to claim 24, wherein the hydroxyl groups of poly(1-hydroxy-1,3-propanediyl) are [is] modified with a monoisocyanate before being crosslinked with a lower alkyl diisocyanate.

27. (Amended) An implant made of a hydrogel according to [any of claims 1 to 26] claim 1.

28. (Amended) An ophthalmic lens made of a hydrogel according to [any of claims 1 to 24] claim 1.

29. (Amended) An ophthalmic lens according to claim 27 having

- (a) an elasticity modulus less than about 10kPa[, preferably less than about 5kPa];
- (b) a tensile strength of at least about 1 MPa;
- (c) an elongation of at least 50% at equilibrium water content;
- (d) sufficient optical clarity so as to obtain an optical transmission of at least about 40%; and
- (e) a refractive index of at least about 1.40.

30. (Amended) A method of preparing a hydrogel having a low elasticity modulus from a hydrophilic polymer comprising the steps of:

- (a) selecting hydrophilic polymer of sufficiently high molecular weight;
- (b) dissolving said polymer in a [good] solvent to a concentration not exceeding about 5% (wt);
- (c) adding a crosslinking agent;
- (d) mixing and reacting the polymer with [crosslinker] the crosslinking agent; and
- (e) evaporating said solvent; and
- (f) optionally adding water.

32. (Amended) A method according to claim 30, wherein the hydrophilic polymer has a molecular weight of at least about 200,000 [200 000, preferably at least about 300 000].

33. (Amended) A method according to claim 30 further comprising degassing the solution of polymer in [good] solvent.

35. (Amended) A method according to claim 30, wherein the hydrophilic [polymers have] polymer has hydroxyl group-carrying carbon-carbon backbone.

36. (Amended) A method according to claim 35, wherein the hydrophilic polymer is [polymers are selected from] at least one [of the polymers] polymer selected from the group consisting of $-(\text{CH}_2-\text{CHOH})_n$ -(polyvinyl alcohol); $-(\text{CH}_2-\text{CH}_2)_n(\text{CH}_2-\text{CHOH})_m$ -(copolymer of ethylene and vinyl alcohol); $-(\text{CH}_2-\text{CH}_2-\text{CHOH})_n$ -(poly(1-hydroxy-1,3-propanediyl)); and $-(\text{CH}_2-\text{CH}(\text{CH}_2\text{OH}))_n$ -(polyallyl alcohol).

37. (Amended) A method according to claim 35 [characterized by] further comprising modifying the hydrophilic polymer by reacting it with a mono-isocyanate.

38. (Amended) A method according to claim 37 [characterized by] comprising modifying less than 15%[, preferably less than 10% of their] of the hydroxyl groups.

39. (Amended) A method according to claim 30 [characterized by] comprising performing the crosslinking at constant volume.

40. (Amended) A method according to claim 30 resulting in the formation of a hydrogel having an elasticity modulus less than about 10 kPa[, preferably less than about 5 kPa].

41. (Amended) A method according to claim 36 wherein the hydrophilic polymer is (poly(1-hydroxy-1,3-propanediyl)).

42. (Amended) A method according to claim 41 wherein the [crosslinker] crosslinking agent is a diisocyanate.